

REMARKS

Claims 1-53 are currently pending. Claims 1, 18, and 35 have been amended to require the substrate to be a water soluble film forming polymeric material. Support for this amendment can be found in the specification at paragraphs 23-24. No new matter has been added upon entry of this Amendment A. Applicants respectfully request allowance of the pending claims.

1. Rejection of Claims 14, 15, 31, 32, 47, and 48 Under 35 U.S.C. §112, first paragraph

Reconsideration is requested of the rejection of claims 14, 15, 31, 32, 47, and 48 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office has stated that the specification fails to clearly describe how to make an endpoint indicator such as required in claims 14, 15, 31, 32, 47, and 48, for use in the water disintegratable cleansing wipe of Applicants' invention. Furthermore, the Office states that it is unaware of any related art which could enable this feature. Applicants respectfully disagree and submit that the specification provides sufficient disclosure of how to obtain an endpoint indicator and further enables the use of the endpoint indicator in the cleansing wipe.

Applicants' claims 14, 15, 31, 32, 47, and 48 are directed to using an endpoint indicator in the water disintegratable cleansing wipe to alert the user that a sufficient amount of time has elapsed for washing of his hands. As further described in the specification, the endpoint indicator is used in combination with the disintegration of the wipe to alert the

user as the endpoint indicator appears just prior to the initial disintegration of the water disintegratable cleansing wipe. Suitable endpoint indicators include, for example, hidden graphic images that appear after sufficient time has elapsed (i.e., graphics as required in claims 15, 32, and 48), color changes that occur after sufficient time has elapsed (i.e., coloring agents as required in claims 15, 32, and 48), and the occurrence of a fizzing or crackling after sufficient time has elapsed. Applicants' specification provides calcium chloride as a specific endpoint indicator for use in the cleansing wipe. Specifically, the calcium chloride can be incorporated into the water disintegratable cleansing wipe to cause a crackling sensation when a sufficient time for washing the hands of the user has elapsed.¹

Furthermore, the specification describes numerous methods of manufacturing a water disintegratable cleansing wipe and incorporating an endpoint indicator into the cleansing wipe. Specifically, in one embodiment, the wipe can be manufactured by introducing the water-soluble film forming polymeric material into deionized water, which may be heated to a temperature of from about 25°C to about 50°C to improve the dissolution rate of the polymeric material. Once introduced into the deionized water, the polymeric material is thoroughly mixed and allowed to hydrate and swell in the water to form a gel-like material. The gel-like material is chilled and cast into a suitable film forming wire, tray, mold, or substrate and dried. After drying, optional agents, such as the endpoint

¹ See Applicants' disclosure at paragraph [0033].

indicator may be introduced onto the dried polymer film through one or various mechanisms known in the art such as, for example, spraying, printing, spreading, and the like.²

Initially, Applicants note that in order to satisfy the enablement requirement, the specification need only disclose sufficient information to enable one skilled in the art to make and use the invention without undue experimentation.³ Specifically, under 35 U.S.C. §112, first paragraph, there is no requirement that, for a patent claim to be enabled, the specification need to teach every detail of the invention or be a production specification.⁴ Furthermore, nowhere in 35 U.S.C. §112, first paragraph, is there a requirement to enable all embodiments of the invention. As noted above, Applicants disclose several methods for incorporating optional components such as the endpoint indicator into the wipe. Furthermore, Applicants provide endpoint indicators such as hidden graphics, color changing agent, and agents that fizz and crackle. Specifically, Applicants provide calcium chloride as an example of an endpoint indicator. As such, Applicants assert that the example of calcium chloride being incorporated into the water disintegratable cleansing wipe to cause a crackling sensation at the appropriate time provides sufficient enablement for one skilled in the art to incorporate an endpoint indicator in the

² See Applicants' disclosure at paragraphs [0038]-[0039].

³ "[T]he specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'...All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art." MPEP §2164.08.

⁴ See Donner, Patent Prosecution: Law, Practice, and Procedure, 4th Ed., vol. II, at p. 1311.

wipe as required in claims 14, 31, and 47.

Furthermore, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.⁵ As disclosed in the specification and claimed in claims 15, 32, and 48, the endpoint indicator to be used in the wipe to alert the user that a sufficient amount of time has elapsed for washing of the skin is a color changing agent or a hidden graphic. Examples of these indicators are well-known in the art. Specifically, as disclosed in U.S. Patent No. 4,793,988, dyes are used as color changing indicators of germicidal activity.⁶ Specifically, prior to the use of a disinfecting composition, the composition has a deep color; however, upon use (i.e., as the composition is used up), the color fades indicating that the composition is effectively killing organisms such as bacteria on a surface.

Based on the foregoing, one skilled in the art could readily prepare a water disintegratable wipe including an endpoint indicator such as a coloring agent or graphic. The specification thus clearly discloses sufficient information to enable one skilled in the art to make and use the invention defined in dependent claims 14, 15, 31, 32, 47, and 48 without undue experimentation. As such, this rejection should be

⁵ See MPEP §2164.05(a), citing to *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

⁶See U.S. 4,793,988 at column 2, line 62 through column 3, line 24, in which a pH sensitive dye such as a pH indicator blue dye can be used to detect germicidal activity.

withdrawn.

2. Rejection of Claims 1-53 Under 35 U.S.C. §112, second paragraph

Reconsideration is requested of the rejection of claims 1-53 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office has stated that as the claims are directed to a cleansing wipe comprising from about 70% (by weight) to about 98% (by weight) or 99% (by weight) of a substrate, the substrate comprising a film forming water soluble polymer material, it is unclear if the wipe has 70% (by weight) to 99% (by weight) of the water soluble polymer material, or if the substrate can be anything impregnated with an undisclosed amount of water soluble polymer material. As suggested by the Examiner, Applicants have amended claims 1, 18, and 35 to require the substrate to be a water soluble film forming polymeric material. As such, the rejection of claims 1-53 should be withdrawn as moot.

3. Rejection of Claims 1-3, 6-9, 11-13, 15-17 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-3, 6-9, 11-13, and 15-17 as being anticipated by Fujita et al. (U.S. 5,062,986).

Claim 1, as amended herein, is directed to a water disintegratable cleansing wipe comprising from about 70% (by weight) to about 99% (by weight) of a substrate and from about 1% (by weight) to about 30% (by weight) of a cleansing agent.

The substrate is a water soluble film forming polymeric material and the cleansing agent comprises a surfactant material. The cleansing wipe is a single layer cleansing wipe and is capable of disintegrating upon contact with water.

Fujita et al. disclose a film-shape soap comprising (a) a water soluble polymer and (b) a soap. The water soluble polymer is suitably a polyester of polyether polyol having an average molecular weight of more than about 1,000 and a polycarboxylic acid. In another embodiment, the water soluble polymer can be methyl cellulose, hydropropyl methyl cellulose, carboxy methylcellulose, hydroxyethyl methyl cellulose, hydroxybutyl methyl cellulose, hydroxy ethyl cellulose, hydroxyl propyl cellulose, polyacrylate, pullulan, polyvinyl alcohol, and the like. The soap is suitably any fatty acid salts usable for soap; however, surfactants other than soaps, for example, an alkyl ester of α -sulfofatty acid salt, an N-acylglutaminic acid salt, alkyl sulfate, alkylbenzenesulfonate, fatty acid isopropanolamide sulfonate, and the like, can also be used to improve the washability, foaming property, soft feeling of the skin, prevention of stimulation, and the like. The water soluble polymer has a weight average molecular weight of not less than about 20,000 and has a rapid soluble time in water.

Significantly, Fujita et al. fail to disclose a water disintegratable cleansing wipe comprising from about 70% (by weight) to about 99% (by weight) of a substrate and from about 1% (by weight) to about 30% (by weight) of a cleansing agent. These are requirements of amended claim 1 and are significant aspects of Applicants' invention.

As stated in M.P.E.P. §2131, a claim is anticipated only if each and every element of the claim is described in the prior art reference. As stated above, the Fujita et al. reference fails to disclose a water disintegratable cleansing wipe. While nowhere in the Fujita et al. reference is a wipe taught or suggested, the Office states that the limitation of a "cleansing wipe" is in the preamble only of the claims, and as such, appears to assert that it is not a structural limitation to be considered for patentability. Applicants respectfully disagree, and assert that the requirement of a "cleansing wipe" imparts a structural limitation to claim 1.⁷

Where an Applicant uses the claim preamble to recite structural limitations of his claimed invention, the Office and courts give effect to that usage.⁸ Whether to treat a preamble as a structural limitation to be considered in evaluating patentability is a determination "resolved only on review of the *entire* [...] *patent* to gain an understanding of what the inventors actually invented and intended to encompass by the

⁷ Additionally, Applicants respectfully submit that the Office cannot simply state that a term is in the preamble of a claim and, without anything further by way of analysis, simply conclude that therefore it is discounted. Applicants submit that the Office should provide some reasoning as to why this term does not provide a structural limitation as opposed to simply stating that it is in the preamble.

⁸ *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Further, any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F2d. 1251 (Fed. Cir. 1989).

claim. (emphasis added)⁹ For example, in Rowe v. Dror, the Federal Court reviewed the specification and drawings of the patent to determine whether those sources convey a clear structural meaning for the claimed preamble phrase "balloon angioplasty catheter". Upon a finding that the *Rowe* specification evinces a particular and distinct structural meaning for "balloon angioplasty catheter" (that of being capable of dilation of coronary arteries), the Court determined that the preamble term "angioplasty" was a structural limitation that distinguished it from the prior art of "balloon catheters".¹⁰ Additional guidelines for determining when to consider the preamble a structural limitation include: when the preamble is essential to understand limitations or terms in the claim body; when the preamble recites additional structure or steps underscored as important by the specification; and when there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art, because such reliance indicates use of the preamble to define, in part, the claimed invention.¹¹

The preamble of claim 1 ("A water disintegratable cleansing wipe comprising...") is necessary to give life, meaning, and vitality to the claim and, as such, should be

⁹ Catalina Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)). The entire patent record includes claims, specification, drawings, and prosecution history. See generally, Rowe, 112 F.3d at 478; Bell Communications Research, Inc., v. Vitalink Communications Corporation, 55 F.3d 615, 621 (Fed. Cir. 1995).

¹⁰ See Rowe, 112 F.3d at 478 (Fed. Cir. 1997).

¹¹ Catalina Marketing, 289 F.3d at 808 (Fed. Cir. 2002).

construed as if in the balance of the claim. See M.P.E.P. §2111.02 and *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Clearly the inventors contemplated inventing a cleansing wipe product for cleaning the skin, since throughout the specification, it is disclosed that the wipe is stored in a dry form and when wetted, absorbs water and begins to swell, releasing the cleansing agent causing the swelling wipe to foam to provide cleaning on the skin.

Further, it is worth noting that in the background of Applicants' specification, Applicants compare their cleansing wipe to conventional wet wipes and state that one advantage of their cleansing wipe is that it can be used even when proper receptacles are not available to dispose of the wipes. As such, the term "cleansing wipe" as used in claim 1 provides a limitation on the claim by limiting and defining the structure of the claimed water disintegratable cleansing wipe. Additionally, Applicants are relying on the preamble during prosecution to distinguish the claimed invention from the prior art. This structural limitation must be considered part of the claim, and, therefore, the preamble must be construed as if in the balance of the claim.

Based on the forgoing, the requirement of claim 1 of a "cleansing wipe" must be considered when evaluating Fujita et al. as prior art.

In addition, as noted above, no where in Fujita et al. is from about 70% (by weight) to about 99% (by weight) substrate, wherein the substrate is a water soluble film forming polymeric material, and from about 1% (by weight) to about 30% (by weight) of a cleansing agent taught or suggested.

Specifically, the only disclosure of amounts of water soluble polymer and soap in the Fujita et al. reference is in the Examples. Specifically, Example 1 discloses preparing a film-shape soap having a blend of 50% (by weight) polymer and 50% (by weight) soap. Furthermore, Example 2 discloses preparing a film-shape soap using 15 grams polymer and 25 grams soap (i.e., a 37.5% (by weight) polymer/62.5% (by weight) soap blend). As such, no where in Fujita et al. is it taught or suggested to use the water soluble film forming polymeric material and cleansing agent in the amounts as required in claim 1 for a cleansing product and, as such, claim 1 is not anticipated and is patentable over the Fujita et al. reference.

Claims 2-3, 6-9, 11-13, and 15-17 depend directly or indirectly on claim 1. As such, claims 2-3, 6-9, 11-13, and 15-17 are novel over the Fujita et al. reference for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

4. Rejection of Claims 4, 5, and 10 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 4, 5, and 10 as being unpatentable over Fujita et al.

Claims 4, 5, and 10 depend on claim 1, which is discussed above. Claim 1 is patentable over the Fujita et al. reference for the reasons set forth above and, as such, claims 4, 5, and 10, which depend from claim 1, are patentable over the Fujita et al. reference for the same reasons as well as for the additional elements they require. Specifically, no where in the Fujita et al. reference is a water disintegratable cleansing wipe comprising from about 70% (by weight) to about

99% (by weight) of a substrate and from about 1% (by weight) to about 30% (by weight) of a cleansing agent taught or suggested. Furthermore, there is no motivation or suggestion to modify the Fujita et al. reference to arrive at a water disintegratable cleansing wipe comprising from about 70% (by weight) to about 99% (by weight) of a substrate and from about 1% (by weight) to about 30% (by weight) of a cleansing agent.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference(s) must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. Applicants respectfully submit that the Office has failed to meet its burden under (1) and (2) above, as Fujita et al. fail to disclose each and every limitation of Applicants' claim 1, and further, there is no motivation or suggestion to modify the Fujita et al. reference to arrive at Applicants' claim 1.

As noted above, Fujita et al. fail to disclose or suggest the water disintegratable cleansing wipe comprising from about 70% (by weight) to about 99% (by weight) of a substrate and from about 1% (by weight) to about 30% (by weight) of a cleansing agent. Furthermore, as the Fujita et al. reference is directed to a film-shape soap for use as a portable type toilet soap or disposable soap, there is no motivation to modify the Fujita et al. reference to arrive at Applicants' water disintegratable cleansing wipe. Specifically, why would one skilled in the art, reading Fujita et al. directed to a

toilet soap, be motivated to modify the composition of Fujita et al. to apply it to a *cleansing wipe*, a completely separate and distinct product, as required in Applicants' claim 1? They simply would not, and could not be so motivated.

Furthermore, as noted above, the Fujita et al. reference fail to disclose from about 70% (by weight) to about 99% (by weight) substrate, wherein the substrate is a water soluble film forming polymeric material, and from about 1% (by weight) to about 30% (by weight) of a cleansing agent. Specifically, as noted above, the only disclosure of amounts of water soluble polymer and soap in the Fujita et al. reference is in the Examples, wherein at least about 50% (by weight) of the film-shape soap is a soap or a surfactant. Why then would one skilled in the art, reading Fujita et al., be motivated to modify these amounts to arrive at the amounts as required in claim 1? Particularly, one skilled in the art would not, and could not, be so motivated as Fujita et al. fail to recognize the use of the water soluble film forming polymeric material and soap composition in a wipe product for use in cleansing the skin.

Because Fujita et al. fail to disclose each and every element of claim 1 and, further, there is no motivation or suggestion to modify the cited reference, claim 1 is patentable over the reference. As such, claims 4, 5, and 10, which depend on claim 1, are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

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PATENT

CONCLUSION

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required to Account No. 19-1345.

Respectfully submitted,

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